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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,742	08/18/2000	Samuel J. Danishefsky	2003080-0054	7338

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/641,742	Applicant(s) DANISHEFSKY ET AL.	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56,58-62,65-67,69-76,78-81,84-86 and 88-102 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 72,91,96 and 99-102 is/are allowed.
- 6) ☒ Claim(s) 56,58-62,65,67,69-71,73-76,78-81,84,86,88-90,92-95,97 and 98 is/are rejected.
- 7) ☒ Claim(s) 66 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 62, 74, 81, 85, 93, 99 and 101 have been amended. Claims 56, 58-62, 65-67, 69-76, 78-81, 84-86 and 88-102 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The rejection of claims 56, 58-62, 65, 67, 69-71, 73-76, 78-81, 84, 86, 88-90, 92-95, 97 and 98 under 35 U.S.C. 102(e) as being anticipated by Danishefsky et al (U.S. 6,660,714) is maintained for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Danishefsky et al discloses the instant glycoconjugates having a peptide backbone made up of at least three amino acids, wherein each occurrence of R_D, R_E and R_F is independently a carbohydrate domain that includes the instant polysaccharides (see claim 6 of ‘714, for example) Danishefsky et al disclose carriers of BSA, polylysine, KLH, tripalmitoyl-S-

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glycerylcysteinylserine and compositions comprising bacterial adjuvants such as BCG, Salmonella minnesota and QS21 which is a saponin (see claims 51, 52, 56 and 57). The disclosure of glycopeptides comprising independent carbohydrate domains encompasses glycopeptides having different carbohydrate domains for R_D , R_E and R_F , which is commensurate with having multiple carbohydrate domains. Danishefsky et al teach the cross linker of claim 65 (see columns 17-18). Thus the disclosure of the '714 patent encompasses constructs which comprises independent carbohydrate domains that are not identical and thus anticipates the instant claims for a multi-antigenic construct..

Applicant argues that the '714 patent discloses structures that are carbohydrate domain attached to natural amino acids such as serine and threonine and not the claimed subject matter of the instant claims which requires a synthetic linkage between the carbohydrate domains and the peptide backbone. This has been considered but not found persuasive. It is noted that the '714 patent discloses the same structural features of the instant claims: for example, claim 1 or the '714 patent versus the instant claim 62. Applicant argues below that the instant claims require at least two carbon atoms between the carbohydrate domain and the peptide backbone by virtue of the limitation in claim 56, wherein $n=1-8$, however this limitation does not exclude the subject matter of the '714 patent. It is noted that the structure of claim 1 of the '714 patent and the structure of the instant claim 62 both utilize a "squiggly" line to indicate attachment of the carbon bearing the carbohydrate domain to the peptide backbone. One of skill in the art would obviously know that the squiggly line is not limited to a single carbon-carbon bond, but is used to indicate some form of attachment. Figure 1 of the '714 patent indicates that link between the carbohydrate domain and an alpha serine carbon facilitate the attachment of the carbohydrate domain to the peptide backbone. This linkage fulfills the specific requirement of the instant claim 56 for $n=1$, and a linkage of two methylene groups. It is further noted that there are no claim limitations in the instant case which would prohibit the use of a peptide comprising all serines so as to accommodate the $n=1$ limitation in claim 56. Thus applicant's arguments that the '714 patent does not encompass structures of the instant invention are unpersuasive.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 56, 58-62, 65, 69-71, 73-76, 78-81, 84, 86, 88-90, 92-95, 97 and 98 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 7,160,856 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '856 patent anticipate the instant claims. It is noted that claims of the patent include multiantigenic constructs because the carbohydrate domains are independently selected from Tn, sTn, sT, etc (see claim 3 of '856).

Applicant argues that the patent discloses structures that are carbohydrate domain attached to natural amino acids such as serine and threonine and not the claimed subject matter

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of the instant claims which requires a synthetic linkage between the carbohydrate domains and the peptide backbone. This has been considered but not found persuasive. It is noted that the '856 patent discloses the same structural features of the instant claims: for example, claim 4 of the '856 patent versus the instant claim 62. Applicant argues below that the instant claims require at least two carbon atoms between the carbohydrate domain and the peptide backbone by virtue of the limitation in claim 56, wherein $n=1-8$, however this limitation does not exclude the subject matter of the '714 patent. It is noted that the structure of claim 1 of the '856 patent and the structure of the instant claim 62 both utilize a "squiggly" line to indicate attachment of the carbon bearing the carbohydrate domain to the peptide backbone. One of skill in the art would obviously know that the squiggly line is not limited to a single carbon-carbon bond, but is used to indicate some form of attachment. The specification can be used as a dictionary to learn the meaning of a term in the patent claim. *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999). Thus, Figure 1 of the '856 patent indicates that link between the carbohydrate domain and an alpha serine carbon facilitate the attachment of the carbohydrate domain to the peptide backbone. One of skill in the art would reasonable conclude that the "squiggly" encompasses a linkage between the carbohydrate domain and the peptide backbone of two carbons. This linkage fulfills the specific requirement of the instant claim 56 for $n=1$, and a linkage of two methylene groups. It is further noted that there are no claim limitations in the instant case which would prohibit the use of a peptide comprising all serines so as to accommodate the $n=1$ limitation in claim 56. Thus applicant's arguments that the '856 patent does not encompass structures of the instant invention are unpersuasive.

The provisional rejection of claims 56, 58-62, 65-67, 69-76, 78-81, 84-86 and 88-102 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 118-129, 132-146, 148-199 of copending Application No. 10/209,618 is withdrawn because of the Terminal Disclaimer in the '618 application.

The provisional rejection of claims 56, 58-62, 65-67, 69-76, 78-81, 84-86 and 88-102 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of copending Application No. 10/728,041 is withdrawn because the '041

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application is the later-filed application and because said application contains a double-patenting rejection over the instant claims.

The rejection of claims 56, 58-62, 65, 67, 69-71, 73-76, 78-81, 84, 86, 88-90, 92-95, 97 and 98 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,660,714 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to the products and compositions used in the method claims of the '714 patent. Thus the instant claims are obvious over the method claims of the patent.

Applicant argues that the claims of the '714 patent are methods of using the glycopeptides of U.S. 7,160,856. This has been considered but not found persuasive. The claims of the '714 patent, although drawn to methods, disclose the same structures as the claims in the '856 patent, and therefore anticipate the instant claims for the same reasons of record as that of the '856 patent.

All other rejections and objections as set forth or maintained in a prior Office action are withdrawn.

Claims 72, 91, 96 and 99-102 are allowable.

Claim 66 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643